IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

VYTACERA BIO, LLC,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. 20-333-GBW-CJB
	)	
CYTOMX THERAPEUTICS, INC.,	)	
	)	
Defendant.	)	

REPORT AND RECOMMENDATION

Presently before the Court in this patent action brought by Plaintiff Vytacera Bio, LLC ("Plaintiff") against Defendant CytomX Therapeutics, Inc. ("Defendant"), is Defendant's Motion for Judgment on the Pleadings, (the "Motion"), (D.I. 164), filed pursuant to Federal Rule of Civil Procedure 12(c). For the reasons set forth below, the Court recommends that the Motion be GRANTED.[1]

I. BACKGROUND

A. Factual Background

Plaintiff alleges Defendant's direct infringement of United States Patent No. 8,809,504 (the "'504 patent") and United States Patent No. 9,775,913 (the "'913 patent") (together with the '504 patent, the "patents-in-suit"). (D.I. 1 at ¶¶ 74-193) Plaintiff asserts that Defendant's Probody™ technology platform ("Probody technology platform" or "Probody technology") infringes claims 1-2, 4, 6-9, 11, 13 and 15-17 of the '504 patent and claims 1-10 and 12-22 of the

[1] This matter was initially referred to the Court for resolution of all pre-trial matters up to and including the end of fact discovery, by former United States District Judge Leonard P. Stark. (D.I. 36) The matter was reassigned to United States District Judge Gregory B. Williams on September 7, 2022. On September 12, 2022, Judge Williams referred the matter to the Court to hear and resolve all pre-trial matters up to and including expert discovery matters (but not including summary judgment motions, Daubert motions, pre-trial motions in limine or the pre-trial conference). (D.I. 161)

'913 patent. (*Id.*) The patents-in-suit cover molecules inhibiting biologically active compounds and further comprising moieties specifically cleavable by a reagent produced by a target cell. (*Id.* at ¶ 1)

B. Procedural History

Plaintiff filed this action on March 4, 2020. (D.I. 1) The Court held a *Markman* hearing on August 23, 2021 and issued a Report and Recommendation regarding claim construction as to four disputed claim terms on October 7, 2021 (the "Claim Construction R&R"). (D.I. 130)[2] The District Judge adopted the Court's recommended construction of all terms at issue on May 9, 2022. (D.I. 155)

Defendant filed the instant Motion on September 23, 2022. (D.I. 164) At the parties' request, the case was stayed pending resolution of the Motion. (D.I. 167) Briefing on the Motion was completed on November 4, 2022. (D.I. 174)

II. LEGAL STANDARD

In evaluating a motion for judgment on the pleadings brought pursuant to Federal Rule of Civil Procedure 12(c), the Court uses the same standard that applies to a motion to dismiss brought pursuant to Rule 12(b)(6). *See Wolfington v. Reconstructive Orthopaedic Assocs. II PC*, 935 F.3d 187, 195 (3d Cir. 2019). It must view all factual allegations in a complaint in the light most favorable to the non-moving party, and it may not grant the motion "unless the movant

[2] A fifth claim term that had been briefed by the parties ("recognition domain") was not well teed up for decision during the initial *Markman* process. (D.I. 106; D.I. 130 at 5) The Court ordered further briefing on that fifth term, (D.I. 131; D.I. 138), and issued a Report and Recommendation on the parties' proposed construction of that term on March 10, 2022, (D.I. 149).

clearly establishes that no material issue of fact remains to be resolved and that he is entitled to judgment as a matter of law." *Id*. (internal quotation marks and citation omitted).

Importantly, when deciding a Rule 12(c) motion, just as with a Rule 12(b)(6) motion, "courts generally consider only the allegations contained in the complaint, exhibits attached to the complaint and matters of public record." *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196 (3d Cir. 1993). Additionally, courts may consider documents that are not attached as exhibits to the complaint if they are nevertheless "integral to or explicitly relied upon in the complaint[.]" *In re Burlington Coat Factory Secs. Litig.*, 114 F.3d 1410, 1426 (3d Cir. 1997) (emphasis omitted); *see also Angstadt v. Midd-West Sch. Dist.*, 377 F.3d 338, 342 (3d Cir. 2004).[3]

III. DISCUSSION

With the Motion, Defendant seeks dismissal of Plaintiff's claims of direct infringement, including claims of literal infringement and of infringement under the doctrine of equivalents

[3] In addressing the Motion, both sides discuss and rely on the content of the Court's Claim Construction R&R (later adopted by the District Judge). Obviously, those claim constructions were not referenced in the Complaint, since the Complaint was filed well before the *Markman* process occurred in this case. Yet, while claim construction can at times involve consideration of extrinsic evidence, it is ultimately a question of law. And, in at least one case, our Court has held that because claim construction is ultimately a legal question, when ruling on a motion for judgment on the pleadings, "the Court may take notice of and rely on its claim construction opinion without converting [a defendant's Rule 12(c) motion] into a motion for summary judgment." *Intellectual Ventures I LLC v. AT & T Mobility LLC*, 235 F. Supp. 3d 577, 588 (D. Del. 2016).

The Court need not assess that issue further here, however, in light of the fact that the parties both agree that the Court may rely upon the Claim Construction R&R in resolving this Rule 12(c) motion. The Court will therefore do so herein.

("DOE").[4] The Court will take up the Motion as it relates to both theories of direct infringement, in turn.

A. Literal Infringement

1. Relevant Legal Standards

"Literal infringement of a claim exists when every limitation recited in the claim is found in the accused device." *Kahn v. Gen. Motors Corp*., 135 F.3d 1472, 1477 (Fed. Cir. 1998). "If any claim limitation is absent from the accused product, there is no literal infringement as a matter of law." *Amgen Inc. v. F. Hoffman-La Roche Ltd*., 580 F.3d 1340, 1374 (Fed. Cir. 2009).

2. The Parties' Arguments

The parties' arguments with regard to the literal infringement claims (and the DOE claims as well) relate to the claim term "inhibitor" (the "inhibitor term") as well as to the claim term "biologically active agent" ("BAA"). These terms (or terms that mean the same thing) are found in all of the asserted claims of the patents-in-suit, but the parties agree that claim 1 of the '504 patent ("claim 1") is representative for our purposes, (*see* D.I. 168 at 4 n.2), and it is reproduced below:

> **1**. An *inhibitor* which is deactivatable by a reagent produced by a target cell comprising:
>
> (a) a first moiety that binds, inhibits, suppresses, neutralizes, or decreases activity of a *biologically active agent* wherein said first moiety is operably linked to;
>
> (b) a second moiety specifically cleavable by a protease produced by a target cell, wherein said first and second moieties are not attached in nature and wherein specific

[4] In addressing the Motion, the parties solely focus on the issue of direct infringement. Plaintiff did accuse Defendant in the Complaint of induced and contributory infringement as to the '913 patent, (D.I. 1 at ¶¶ 121, 183-89), but of course an element of such claims is that there must have been direct infringement in the first place. And so the Court, as do the parties, will focus solely on the allegations regarding direct infringement herein.

> cleavage of said second moiety causes reduction of binding activity of said *inhibitor*.

('504 patent, col. 83:11-20 (emphasis added))

Defendant's argument about why Plaintiff has not sufficiently pleaded a claim of literal infringement of claim 1 (and all other asserted claims) goes as follows:

- In its Claim Construction R&R, the Court construed "inhibitor" to mean "*a molecule, separate from* the [biologically active agent/antibody], having the ability to bind, inhibit, suppress, neutralize, or decrease activity of a [biologically active agent/antibody]." (D.I. 130 at 8 (bracketed text in original, emphasis added)); *see also* D.I. 155 at 2-6) The Court's construction made clear that the inhibitor must be a separate molecule from the BAA. (D.I. 155 at 2 (noting, in setting out the construction for the inhibitor term, that the "inhibitor and the BAA must always be separate molecules"); *see also* D.I. 130 at 6) (same))

- The operative Complaint depicts the structure of the accused Probody technology platform; the pictures included therein show how the asserted inhibitor and BAA in the accused product are part of the same molecule. (D.I. 165 at 7-8 (citing D.I. 1 at ¶¶ 92, 94))

- Numerous of Defendant's documents cited in and relied on by the Complaint indicate that the accused inhibitor and BAA in the Probody technology platform are a part of the same molecule. (*See, e.g.*, D.I. 166, ex. C at 8 (noting that "Probody therapeutics are produced as a *single protein*" and that the therapeutic includes a "protease-cleavable linker [i.e., the accused second moiety] which *connects* the mask [i.e., the accused first moiety] to the antibody [i.e., the accused BAA]") (emphasis added) (cited in D.I. 1 at ¶¶ 55-63); *id*., ex. F. at 7 (noting that Probody therapeutics consist*, inter alia*, of a "protease-cleavable linker which *tethers* the mask to the antibody") (emphasis added) (*cited in* D.I. 1 at ¶¶ 55-63); *see also* D.I. 165 at 10-11)

- Thus, Defendant argues that it is clear that the accused product cannot literally satisfy all of the limitations in the asserted claims since, *inter alia*, that product does not make use of an inhibitor.

(D.I. 165 at 5-11, 13-15)

In response, Plaintiff does not dispute that this is what the Complaint alleges. (D.I. 168 at 4 (Plaintiff agreeing that the accused product is shown in the Complaint using a "single protein") (quotation marks omitted); *see also* D.I. 174 at 1-2, 6) Instead, Plaintiff posits a new theory: that Defendant's "[p]robodies do not exist as a single molecule throughout the manufacturing process" and so they could meet the claims' requirements at that stage. (D.I. 168 at 4) Plaintiff then goes on to cite to numerous documents and pieces of evidence nowhere mentioned in or attached to the Complaint, in an effort to explain this theory. (*Id*. at 4-10)

The Court, however, cannot consider these new arguments and never-before-cited documents in resolving this Rule 12(c) motion. That is because none of the key asserted facts relied on by Plaintiff are pleaded in the Complaint, and all but one of the cited documents are not attached to the Complaint, referenced in the Complaint or otherwise integral to the Complaint. (D.I. 174 at 5 (Defendant noting that Plaintiff's new theory—i.e., that an alleged "transient manufacturing intermediate" could amount to an inhibitor—is a "wholly unpled" theory)); *Ford v. Keystone Hum. Servs.*, Civ. No. 22-682-GBW, 2023 WL 6295227, at *3 (D. Del. Sept. 27, 2023) (noting that "a complaint may not be amended through an opposition brief and new facts may not be considered by a court ruling on a motion to dismiss"); *Chavez v. Dole Food Co.*, Civil Action No. 12-697-RGA, 2019 WL 3207649, at *5 (D. Del. July 16, 2019) (declining to consider documents outside of the pleadings in resolving a Rule 12(c) motion), *report and recommendation adopted*, 2019 WL 9091768 (D. Del. Sept. 4, 2019).[5] Therefore, the Court recommends that the Motion be GRANTED as to Plaintiff's claims of literal infringement.

[5] The fact that Plaintiff is relying on a wholly unpleaded theory here matters, and not just because doing so technically violates the rules for considering Rule 12(c) motions. Defendant asserts that some of the documents that Plaintiff cites in support of its new literal

B. Doctrine of Equivalents

1. Relevant Legal Standards

"Even when an accused product does not meet each and every claim element literally, it may nevertheless be found to infringe the claim if there is 'equivalence' between the elements of the accused product or process and the claimed elements of the patented invention.'" *Intendis GMBH v. Glenmark Pharms. Inc., USA*, 822 F.3d 1355, 1360 (Fed. Cir. 2016) (certain internal quotation marks and citations omitted). The DOE is applied to individual elements of the claim, not to the invention as a whole. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co*., 520 U.S. 17, 29 (1997).

There are two frameworks for establishing equivalence: (1) the function-way-result ("FWR") test; and (2) the "insubstantial differences" test. *Mylan Institutional LLC v. Aurobindo Pharma Ltd.*, 857 F.3d 858, 866-67 (Fed. Cir. 2017). "To succeed on a [DOE] theory, the patentee must demonstrate equivalence under one these two tests." *Brilliant Instruments, Inc. v. GuideTech, LLC*, 707 F.3d 1342, 1347 (Fed. Cir. 2013). The FWR test requires the patentee "to show, for each claim limitation, that the accused product 'performs substantially the same function in substantially the same way with substantially the same result as each claim limitation of the patented product.'" *Id.* (citation omitted). The insubstantial differences test asks whether

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infringement theory: (1) are a part of Defendant's Investigational New Drug Application, such that reliance on them is precluded by law; or (2) demonstrate that the theory relies on alleged infringement occurring outside of the United States. (D.I. 174 at 6, 9) If Defendant's arguments here were correct, then it very much would matter which of the documents Plaintiff refers to in its briefing were or were not cited in Plaintiff's relevant complaint. This is one of the reasons why parties actually have to plead facts regarding their theories of infringement in their complaint—i.e., because the viability of a pleaded theory could very much depend on the particular facts the plaintiff chooses to reference or the particular documents the plaintiff chooses to cite in support. Here though, since Plaintiff included in the Complaint essentially none of the facts or documents at issue here with its new theory, the Court cannot know whether any such allegations (had they been pleaded) could have withstood Defendant's challenge.

the accused product or process is substantially different from what is patented. *Mylan Institutional LLC*, 857 F.3d at 866.

However, a patentee's use of the DOE has its limits. A DOE theory cannot be used: (1) "to expand a patentee's narrowly defined claim element[,]" (2) "when a patent explicitly or implicitly excludes subject matter[,]" or (3) "to redefine, read out, or vitiate a claim limitation." *AstraZeneca UK Ltd. v. Watson Lab'ys, Inc. (NV)*, 905 F. Supp. 2d 596, 599 (D. Del. 2012).

2. The Parties' Arguments

Defendant moves for dismissal of any claims in which Plaintiff asserts that Defendant is guilty of direct infringement under the DOE. It asserts that because its Probody technology platform utilizes a unitary molecule, and because the Court's construction of the inhibitor term makes clear that the inhibitor and the BAA must always be separate molecules, then any DOE infringement read would vitiate the inhibitor limitation. (D.I. 165 at 16-17) In response, Plaintiff states that Defendant's accused product could well be understood to be the equivalent of a product wherein the inhibitor and the BAA are separate molecules. (D.I. 168 at 13-15) And in its briefing, Plaintiff provides some explanation of its theory in this regard. There, Plaintiff argues that an application of the FWR test demonstrates that it is "clear that infringement can be found under the DOE." (*Id*. at 14) Additionally, Plaintiff contends that "the physical connection between the Probody's mask [i.e., the alleged first moiety] and the antibody [i.e., the alleged BAA] is an insubstantial difference[.]" (*Id*. at 15)

The problem here is that Plaintiff did not sufficiently plead a theory of infringement pursuant to the DOE in the Complaint. Instead, in the respective counts, Plaintiff simply wrote that the Probody technology platform infringes the asserted claims "literally and / or under the doctrine of equivalents"—and then went on to say nothing more about how it was plausible that

the DOE applied here. (D.I. 1 at ¶¶ 75, 121) Indeed, the Complaint is entirely focused on literal infringement of the asserted claims. (*See id*. at ¶¶ 74-193)

In the Court's view, a plaintiff must plead facts that articulate why it is plausible that a defendant's accused product infringes under the DOE. After all, a claim of patent infringement is subject to the *Twombly*/*Iqbal* pleading standard. And if a Court cannot understand why it is plausible that a defendant infringes a patent, then it cannot articulate how or why a challenged claim of patent infringement has withstood a Rule 12 challenge. *See, e.g., DIFF Scale Operation Rsch., LLC v. MaxLinear, Inc*., Civil Action No. 19-2109-LPS-CJB, 2020 WL 2220031, at *1 (D. Del. May 7, 2020) (citing cases), *report and recommendation adopted* 2020 WL 6867103 (D. Del. Nov. 23, 2020). So far as the Court can reason, there is nothing magical about a claim of direct patent infringement pursuant to the DOE that suggests that it should be treated differently for pleading purposes than any other type of claim under the law.[6] *See Nalco Co. v. Chem-Mod, LLC*, 883 F.3d 1337, 1354 (Fed. Cir. 2018) (concluding that a plaintiff adequately stated a DOE claim of infringement "under the *Twombly* and *Iqbal* pleading standard" when it incorporated detailed infringement contentions into its pleading, which explained its DOE claim and how defendants' use of the accused solution satisfied the FWR test); *see also Niazi v. Merit Med. Sys., Inc.*, No. 3:16-cv-00668-jdp, 2016 WL 9225364 (W.D. Wis. Nov. 16, 2016) (finding a DOE infringement allegation wanting where the plaintiff simply alleged that the accused products "infringe . . . either literally or under the doctrine of equivalents[,]" without describing

[6] Put differently, if at the Rule 12 stage a plaintiff is asserting that it has stated a plausible claim of direct infringement under the DOE, but the Court cannot understand how what is pleaded actually makes out a plausible claim in that regard, it does not make any sense that the plaintiff could overcome this objection by saying "Well, I used the phrase 'doctrine of equivalents' once in my pleading, so you must deny the opposition's Rule 12 motion." Were that the law, it would be akin to saying that a plaintiff does not need to establish a plausible DOE claim—and instead need only type in a talismanic three-word phrase to get over the pleading bar.

how the products actually were said to infringe under the DOE); *Macronix Int'l Co. v. Spansion Inc.*, 4 F. Supp. 3d 797, 804 (E.D. Va. 2014) (rejecting a plaintiff's DOE infringement allegations that were pleaded in "bare bones, conclusory form"); (D.I. 174 at 3). Nor is this a scenario like that in *Disc Disease Solutions Inc. v. VGH Solutions, Inc.*, 888 F.3d 1256 (Fed. Cir. 2018), where a plaintiff need not rely on a narrative articulation of how the accused products plausibly infringe under the particular theory of direct infringement because the answer is otherwise clear from the record. *DIFF Scale Operation Rsch., LLC*, 2020 WL 2220031, at *1 n.2 (citing *Disc Disease*, 888 F.3d at 1257-60).

Indeed, especially after the *Markman* hearing in this case, the answer is decidedly *not* clear from the record. Since the Court's construction of the inhibitor term states that an inhibitor must be a "molecule, *separate from*" the BAA, and since Plaintiff's DOE theory is that the inhibitor and the BAA can be a part of the *same* molecule, on its face this sure seems like a situation where finding equivalence under Plaintiff's theory could "require a determination [of] the very thing that the construction of ['inhibitor'] excludes." *Augme Techs., Inc. v. Yahoo! Inc.*, 755 F.3d 1326, 1335 (Fed. Cir. 2014). If that were so, then a claim of infringement under the DOE could not stand, since "[t]he concept of equivalency cannot embrace a structure that is specifically excluded from the scope of the claims." *Id*. (internal quotation marks and citation omitted); *see also* (D.I. 165 at 16-17); *Cumberland Pharms. Inc. v. Sagent Agila LLC*, C.A. No. 12-825-LPS, 2013 WL 5913742, at *3 (D. Del. Nov. 1, 2013).

Now, maybe it is possible that—despite the Court's construction of the inhibitor term and despite the nature of Plaintiff's apparent (unpleaded) DOE theory—Plaintiff could still somehow articulate a viable DOE-based direct infringement claim in this case. *Cf. Bio-Rad Laby's, Inc. v. 10X Genomics Inc.*, 967 F.3d 1353, 1367-68 (Fed. Cir. 2020) (rejecting the argument that a jury

wrongly concluded that fluorinated microchannels are equivalent to a limitation requiring "non-fluorinated microchannels[,]" because trial evidence indicated that a reasonable juror could have found that a negligibly-fluorinated microchannel performed the same function, in the same way and achieved the same result as a non-fluorinated microchannel). The Court is not sure. But the point is that even if it were possible, under these circumstances, the theory would need to be *plausibly set out* in the operative pleading. Yet here, it is not; the Complaint makes no mention of such a theory or facts in support thereof. This is underscored by the fact that when Plaintiff discusses the theory in its briefing, it cites to no portion of the record in doing so. (D.I. 168 at 10-16; *see also* D.I. 174 at 2 (Defendant faulting Plaintiff for doing nothing more than pointing to a "rote recitation of the words 'doctrine of equivalents'" in attempting to plead this claim in the Complaint))

Therefore, the Court recommends that the Motion be GRANTED as it regards any claim of direct infringement made pursuant to the DOE.

IV. CONCLUSION

For the foregoing reasons, the Court recommends that Defendant's Motion be GRANTED.[7]

This Report and Recommendation is filed pursuant to 28 U.S.C. § 636(b)(1)(B), Fed. R. Civ. P. 72(b)(1), and D. Del. LR 72.1. The parties may serve and file specific written objections within fourteen (14) days after being served with a copy of this Report and Recommendation. Fed. R. Civ. P. 72(b)(2). The failure of a party to object to legal conclusions may result in the loss of the right to *de novo* review in the district court. *See Sincavage v. Barnhart*, 171 F. App'x 924, 925 n.1 (3d Cir. 2006); *Henderson v. Carlson*, 812 F.2d 874, 878-79 (3d Cir. 1987).

[7] Defendant's request for oral argument on the Motion, (D.I. 175), is DENIED.

The parties are directed to the Court's Standing Order for Objections Filed Under Fed. R. Civ. P. 72, dated October 9, 2013, a copy of which is available on the District Court's website, located at http://www.ded.uscourts.gov.

Dated: October 30, 2023

Christopher J. Burke
Christopher J. Burke
UNITED STATES MAGISTRATE JUDGE